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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,952	01/16/2007	Nicole Mekideche	0040-0164PUS1	2854
2292 7590 09/11/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
TATE, CHRISTOPHER ROBIN				
ART UNIT		PAPER NUMBER		
1655				
NOTIFICATION DATE		DELIVERY MODE		
09/11/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/596,952

Applicant(s)

MEKIDECHE, NICOLE

Examiner

Christopher R. Tate

Art Unit

1655

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-18 and 20-28 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-18 and 20-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed 14 July 2008 is acknowledged and has been entered.

Claims 10-18 and 20-28 have been examined on the merits (claims 1-3 and 5-9 remain withdrawn at this time).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 10-18 and 21-28 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, for the reasons set forth in the previous Office action.

Applicant's arguments have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicant argues that while it is true that the working examples in the application only relate a topical composition comprising dedifferentiated cells obtained from *Critimum maritimum* (as the active ingredient therein), the Examiner's singular focus on the working examples is misplaced and improperly fails to consider the other teachings in the application that provide those skilled in the art with a disclosure sufficient to enable one skilled in the art to practice the full scope of Applicant's invention, including because instant Examples 1, 2, and 4 provide such enablement. Thus, the Examiner merely makes conclusory statements that "the scope of the claims is clearly beyond the scope of the instantly claimed/disclosed invention" or that "it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the instantly claimed composition".

However, as readily admitted within the instant specification (see, e.g., page 4, lines 29-35, of the instant specification), "Applicant has discovered in a surprising and unforeseen way that a lyophilisate of dedifferentiated plant cells allows to achieve this combination of desired effects: the depigmenting and/or lightening of the epidermis with a total innocuousness, while the epidermis is benign protected and regenerated". It should be noted, however, these "surprising and unforeseen" *in vivo* therapeutic functional effects to the skin have only been demonstrated by Applicant using a topical composition comprising dedifferentiated *Critimum maritimum* cells as the active ingredient therein, but not one which comprises dedifferentiated cells from any and all halophilic plants within the entire plant kingdom (as encompassed by most of the instant claim language) nor from the multitude of halophilic plants recited by new claim 25 therein. In this regard, the application disclosure and claims were compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art;

In view of the singular use of dedifferentiated cells obtained from the halophilic plant *Critimum maritimum* as the active ingredient within the demonstrated therapeutic topical cream - as shown in instant Examples 1-6 (so as to provide the surprising and unforeseen way of achieving the combination of desired effects - i.e., depigmenting and/or lightening of the

epidermis with a total innocuousness, while the epidermis is benign protected and regenerated), those skilled in the art are unlikely to accept the instant data as being correlatable to using dedifferentiated plant cells from any and all halophytic plants encompassed and/or recited by the instant claim language, so as to successfully provide the combination of unforeseen and surprising *in vivo* therapeutic functional effects to the skin when topically applied thereto. Further, the state of the prior art does not appear to recognize using dedifferentiated cells from halophilic plants for the intended combined therapeutic purposes instantly claimed/disclosed.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use a topical composition comprising dedifferentiated cells from any and all halophilic plants (including the multitude of halophilic plants recited by new claim 25) so as to successfully provide the combination of *in vivo* therapeutic functional effects to the skin when topically applied thereto, other than employing dedifferentiated cells obtained from *Critimum maritimum* as the active ingredient therein.

Claim Rejections - 35 USC § 103

Claims 10-18 and 20-28 are/stand rejected under 35 U.S.C. 103(a) as being unpatentable over Majmudar (US 2005/0123499) in view of Ennamany (WO 03/077881 - Derwent Abstract and machine translation provided by EPO) - for the reasons set forth in the previous Office action.

Claims 10-18 and 21-24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mikimoto (JP 2003-160461 - Derwent Abstract) in view of Ennamany (WO 03/077881 - Derwent Abstract and machine translation provided by EPO) with evidence provided by the NPS website - for the reasons set forth in the previous Office action.

Applicant's arguments have been carefully considered but are not deemed to be persuasive of error in the above art rejections. With respect to the first USC 103 rejection above, Applicant argues that Majmudar discloses a composition comprising sea fennel (*Criste marine*) - as an active skin therapeutic therein, but that this reference does not in any way teach or suggest compositions having a depigmenting effect on the epidermis. Thus, the purpose and effects of the compositions taught by Majmudar are clearly different from those of the present invention. However, please note that the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use would be intrinsic to the composition reasonably suggested by the combined teachings of the cited references (see, e.g., MPEP 2112). Applicant further argues that the primary references cited within the two USC 103 rejections above do not in any way teach or suggest the use of dedifferentiated plant cells, or a lyophilisate thereof. However, this is why the claims were rejected under USC 103 - i.e., in view of the beneficial teachings provided by the secondary reference of Ennamany (as discussed within each of the USC 103 rejections of record). Applicant also argues that Ennamany is directed to cosmetic compositions containing at least one phytoalexin, which are effectively antibiotics that are synthesized as a defense mechanism of the living cells in response to exposure to pathogens - which is far different from the present invention wherein the

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dedifferentiated plant cells are from halophytic plant cells capable of tolerating high salinity, and that the teachings of Ennamany are limited to the plant genera described therein at, e.g., paragraph [0112]. However, the overall teachings of Ennamany are clearly not limited to cosmetic compositions containing phytoalexin(s) therein - i.e., Ennamany teaches the production of topical compositions which are rich in natural plant metabolites (from whatever plant is employed therein) due to being produced by dedifferentiated plant cells in vitro which are freeze-dried (lyophilized), milled, and dispersed within such cosmetic compositions. Thus, Ennamany provides clear motivation to one of ordinary skill in the art to employ essentially any cosmetically-valuable (e.g., having skin therapeutic activity) plant therein - based upon the many advantages Ennamany expressly teaches with respect to a final cosmetic composition comprising such dedifferentiated lyophilized plant cells therein. Further, Ennamany discloses that by dedifferentiated plant cells, one understands any vegetable cell not presenting characters of specialization that is able to live by itself and not in dependence with other cells is suitable for use therein. Accordingly, employing particular skin therapeutic plants (such as those disclosed by the primary references in each of the above USC 103 references) in the form of dedifferentiated lyophilized preparations within such cosmetic compositions (including within the instantly claimed amounts/amount ranges - based upon the amount ranges beneficially disclosed by Ennamany) would have been obvious to one of ordinary skill in the art at the time the claimed invention was made based upon the beneficial teachings provided by Ennamany, for the reasons fully discussed in the previous Office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The examiner assigned to this Application has changed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher R. Tate/
Primary Examiner, Art Unit 1655